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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/538,130	06/29/2006	Ghislaine Tissot	09879-00064-US	1355
23416 7590 05/19/2009 CONNOLLY BOVE LODGE & HUTZ, LLP P O BOX 2207 WILMINGTON, DE 19899				
EXAMINER				
KUBELIK, ANNE R				
ART UNIT		PAPER NUMBER		
1638				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/538,130

Applicant(s)

TISSOT ET AL.

Examiner

Anne R. Kubelik

Art Unit

1638

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 06 April 2009.
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 1-16 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SF/ICE)
Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 6 April 2009 has been entered.
2. Claims 1-16 are pending.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 1-3, 6-8 and 13-15 are rejected under 35 U.S.C. 102(e) as being anticipated by Daniell (US Patent 7,129,391, filed 15 May 1998). The rejection is repeated for the reasons of record as set forth in the Office action mailed 9 October 2008. Applicant's arguments filed 6 April 2009 have been fully considered but they are not persuasive.

Daniell claims soybean, peanut and pea plants whose chloroplasts are stably transformed (claims 75-77 and 81-83) and a method of producing them (claim 92). Daniell indicates that stably transformed plants have progeny with the transformation event (column 7, line 10-13);

thus, the plants must be fertile. The process inserts the expression cassette into an intergenic region (claim 84) and was done by particle bombardment (column 27, lines 39-67).

Daniell also claims plastid transformation vectors comprising an expression cassette encoding a selection marker two sequences homologous with a portion of a legume plastome, wherein the sequences flank an expression cassette encoding a peptide of interest (claims 3 and 95); the flanking sequences are homologous because they are competent to undergo homologous recombination with the plastid sequence of the target plant, and because they are used to produce the plastid-transformed soybean, peanut and pea plants of claims 75-77 and 81-83). The expression cassettes comprise 5' and 3' expression control sequences (claims 3 and 84), which include a Prn promoter and a psbA terminator (Fig 2).

Applicant urges that the patent does not enable fertile transplastomic leguminous plants (response pg).

This is not found persuasive because the issued claims are drawn to soybean, peanut and pea plants whose chloroplasts are stably transformed; '391 indicates that stably transformed plants have progeny with the transformation event (column 7, line 10-13).

Applicant urges that the patent uses a universal vector to transform soybeans and peanuts, but there is no disclosure of fertile transplastomic soybean and peanut plants (response pg 2-3).

This is not found persuasive because the issued claims are drawn to soybean, peanut and pea plants whose chloroplasts are stably transformed. Thus, there is disclosure of fertile transplastomic soybean, peanut and pea plants.

Applicant urges that Verma et al indicates that transformation of potato and tomato with tobacco vectors and of tobacco with petunia vectors had a low efficiency of transformation; they concluded a universal vector will be less efficient than species specific vectors (response pg 3).

This is not found persuasive because Verma et al did not address legume plastid transformation, and did not say that fertile transplastomic soybean, peanut and pea plants could not be obtained. Further, a lower efficiency is not the same thing as not working.

Applicant urges that legume transformation would be even less efficient; Dufourmantel et al noted that the soybean plastid sequences were organized differently than tobacco (response pg).

This is not found persuasive. A lower efficiency does not mean that that the claims of '391 are not enabled. Further, the *rbcL* and *accD* genes are not in '391's universal vectors. Any difference between publicly available sequences and any sequences identified by the authors does not mean that '391's claims are not enabled.

Applicant urges that the statements in Verma et al imply that '391 does not disclose fertile transplastomic leguminous plants (response pg 4).

This is not found persuasive. Issued claims are presumed enabled. The standard for showing that the issued claims of a patent are not enabled is much higher than implication.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 1-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Maliga et al (1999, US Patent 5,877,402) in view of von Allmen (1992, GenBank Accession No. X07675). The rejection is repeated for the reasons of record as set forth in the Office action mailed 9 October 2008X. Applicant's arguments filed 6 April 2009 have been fully considered but they are not persuasive.

The claims are drawn to fertile transplastomic legumes, including soybeans, wherein the plants have been transformed with a plastid transformation vector comprising expression cassettes flanked by soybean plastid sequences from a region encoding the rRNA, trnV and rps12.

Maliga et al teach a method of tobacco plastid transformation by particle bombardment using a vector comprising expression cassettes comprising the aadA selection marker and a gene of interest, each operably linked to a plastid promoter and plastid terminators, wherein the expression cassettes are flanked by tobacco plastid sequences from a region encoding the 16S rRNA, trnV and rps12/7 (column 22, lines 13-30, column 22, line 59, to column 25, line 67; column 27, lines 14-59; column 51, line 59, to column 57, line 40; Fig 17C, 18, 19, 22). McBride et al do not disclose a method of soybean plastid transformation a vector comprising expression cassettes comprising the aadA selection marker and a gene of interest, each operably linked to a plastid promoter and plastid terminators using a vector comprising expression cassettes flanked by soybean plastid sequences from a region encoding the 16S rRNA, trnV and rps12.

von Allmen teaches the sequence of the portion of the soybean plastid genome that encodes the 16S rRNA, trnV and rps12.

At the time the invention was made, it would have been obvious to one of ordinary skill in the art to modify the method of plastid transformation as taught by McBride et al, to replace the tobacco flanking regions with the corresponding ones from soybean plastid as described in von Allmen. One of ordinary skill in the art would have been motivated to do so because plastid transformation works by homologous recombination (Maliga et al, column 21 lines 30-45), and one of skill in the art would know that the higher the homolog between the targeting segment and the target, the higher the probability of transformation. Thus, one of skill in the art would wish to use a vector comprising soybean plastid targeting sequence when transforming soybean. One of skill in the art would use targeting sequences based on the sequence taught by von Allmen because it corresponds to the region Maliga et al has shown works effectively in tobacco and because the sequence for that region is readily available. Maliga et al teaches that the targeting segment should be relatively large (column 21. lines 46-55); thus one of skill in the art would use SEQ ID NO:1 and 2, or similar sequences, made by isolating the DNAs by PCR using primers based on von Allmen's sequence. The exact breakpoint would be one of personal choice, and one of skill in the art would reasonably choose the breakpoint such that one flanking region comprises the 16SrRNA and a portion of trnV and the other comprises the rest of trnV and rps12/7.

Applicant urges that it was well-known that application of transplastomic technology to plants other than tobacco was hindered by limitations in transformation protocols and tissue culture systems, which Maliga et al recognized (response pg 5).

This is not found persuasive because at no place does Maliga et al say it is not possible to transform soybean or any other legume.

Applicant urges that even if one of skill in the art were motivated to combine Maliga et al with von Allmen, he would not have been able to regenerate fertile transplastomic plants, because methods for regenerating them were unknown, due to art-recognized obstacles relating to plastid transformation technology and regeneration protocols; thus, one of skill in the art had no reasonable expectation of success (response pg 5).

This is not found persuasive. Applicant has not pointed to any nonobvious step required for regenerating fertile transplastomic plants, nor are any such steps in the method claims.

Applicant urges that prior to the present application no one had obtained fertile transplastomic leguminous plants, citing Daniell 2005 and Zhang (response pg 14).

This is not found persuasive. '391 claimed stably transformed transplastomic leguminous plants.

Conclusion

7. All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however,

will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne R. Kubelik, Ph.D., whose telephone number is (571) 272-0801. The examiner can normally be reached Monday through Friday, 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg, can be reached at (571) 272-0975.

The central fax number for official correspondence is (571) 273-8300.

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For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

May 19, 2009

/Anne R. Kubelik/
Primary Examiner, Art Unit 1638